REMARKS/ARGUMENTS

Claims 17 and 19-57 are pending in this Application. The Office Action mailed on January 16, 2008 included the following rejections:

1. Claims 47 and 49-57 are rejected under 35 U.S.C. § 112 First paragraph.
2. Claims 17, 21-25 and 34-41 are rejected under 35 U.S.C. § 103.
3. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.
4. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.

Applicant respectfully addresses the basis for each of the rejections below.

Claims 42-46 are rejected under 35 U.S.C. 112 Second paragraph.

The Office Action rejects Claims 47 and 49-57 are rejected under 35 U.S.C. § 112 First paragraph. Specifically stating

> The claims recite obtains mutation from the n-heptanoic acid through an odd carbon". In the specification, para 0076 states a nutritional supplement to a dietary formula comprising low fat and/or reduced long chain fatty acid. From this statement the reduced chain fatty acid can be odd or even. Applicant is advised to show where in the specification that is recited.

Applicant is unclear to what the Office Action is referring to in the statement

> claims recite obtains mutation from the n-heptanoic acid through an odd carbon
>
> In the specification, para 0076 states a nutritional supplement to a dietary formula comprising low fat and/or reduced long chain fatty acid.

The claims do not recite the term "mutation" and although paragraph 0076 does recite the

"…low fat and/or reduced long-chain fatty acids" this is not claimed in claims 47 and 49-57.

The claims at issue are claims 47 and 49-57, which are fully supported by the specification as filed. Applicant submits that the β-oxidation of odd-numbered chains is well known in the art and the skilled artisan is familiar with the metabolism cycle of odd-numbered fatty acids chains.

Claims 47 and 49-57 fully comply with the written description requirement. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-564, 19 USPQ2d 1111, 1116-117 (Fed. Cir. 1991) and In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

Claim 47 provides a method for providing fuel to heart tissue of a patient, comprising administering to said patient a n-heptanoic acid composition whereby said heart tissue rapidly obtains nutrition from the n-heptanoic acid composition through an odd carbon fatty acid metabolism. Claim 47 and claims 49-52 are fully supported throughout the Specification as filed. For example, paragraph [0012] discloses the method is suitable for treating cardiac disorders such as cardiac myopathy. It is also suitable for treatment of the aftermath of heart surgery, wherein the compound or derivative is utilized for direct fueling of heart muscle. Paragraph [0013] discloses the present invention is a dietary formulation suitable for treatment of heart tissue in cardiac or surgical patients comprising a seven–carbon fatty acid chain, wherein the seven-carbon fatty acid chain is characterized by the ability to transverse the inner mitochondrial membrane by a transport mechanism which does not require carnitine palmitoyltransferase I, carnitine palmitoyltransferase II, or carnitine/acylcarnitine translocase and the ability to undergo mitochondrial β-oxidation, and wherein the compound is selected from the group consisting of n-heptanoic acid or a derivative thereof, a triglyceride comprising n-heptanoic acid or a derivative thereof, and triheptanoin or a derivative thereof.

Similarly claim 53 and dependent claims 54-57 are supported by the specification as

filed. Claim 53 provides a method for treating a patient in need of treatment for a severe translocase deficiency by providing a patient suffering from one or more symptoms of severe translocase deficiency; and administering to the patient a therapeutically effective amount of a n-heptanoic acid composition comprising n-heptanoic acid, triheptanoin, 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate; 5-methylhexanoate, 5-methyhexenoate and 3-hydroxy-5-methylhexanoate or combination thereof sufficient to overcome the severe translocase deficiency.

The specification as filed fully complies with the written description requirement. For example, paragraph [0080] discloses the treatment of translocase deficiencies by administering n-heptanoic acid. Specifically, stating "the addition of n-heptanoic acid to cultured cells (fibroblasts) taken from patients with a lethal form of translocase deficiency indicated successful oxidation." In addition, paragraph [0080] states, "based on the successful metabolism of n-heptanoic acid by the two cell lines having severe translocase deficiency, the tandem mass spectrometry assay was performed on fibroblast cell lines taken from normal patients and from patients affected by the following inherited defects of fat oxidation as proven by direct enzyme assay in other collaborating laboratories…" Furthermore, claim 6 of the application as filed defines the composition derivative as being selected from the group consisting of 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate, 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy-5-methylhexanoate. As a result, claim 53-57 are fully supported in the specification as filed, do not introduce new matter and full comply with the written description requirement.

Applicants submit that the claims fully comply with the written description requirement and respectfully request withdrawal of the rejection.

Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over U. S. Patent Application No.10/748,432.

The Examiner states the subject matter claimed in the instant application is disclosed in

the Patent Application Number 10/748,432 and is claiming common subject matter with the instant application. Applicants assert that a terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over U. S. Patent Application No.10/371,385.

The Examiner states the subject matter claimed in the instant application is disclosed in the Patent Application Number 10/371,385 and is claiming common subject matter with the instant application. Applicants assert that a terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).

Conclusion

In light of the remarks and arguments presented above, Applicant respectfully submits that claims 17, 19-47 and 49-57 are pending in this application. Applicant submits that this application is in condition for allowance. Favorable consideration and allowance of the pending claims are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: August 18, 2008.

Respectfully submitted,

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